REMARKS

Status of the Claims

Claims 1-26 are pending in this application. Claims 1-22 and 26 have been withdrawn from consideration.

Claims 23-25 stand rejected. Claims 23 and 25 are amended. No new matter is introduced by the amendments.

Claim Rejections

The Examiner has rejected claims 23 and 25 under 35 U.S.C. § 102(b) as anticipated by Gennaro (Remington: The Science and Practice of Pharmacy). Claim 24 is rejected under 35 U.S.C. § 103 as obvious over Gennaro in view of either U.S. Patent No. 5,637,313 to Chau et al. or U.S. Patent No. 4,812,303 to Iorio. Specifically, the Examiner states that Gennaro teaches a "process of wet granulation compris[ing] mixing the tablet ingredients in a high shear mixer followed by drying in a flat bed oven, such as a fluidized bed oven." The Examiner cites Chau et al. and Iorio as disclosing the incorporation of calcium carbonate as an ingredient in various conventional tablets. Applicants respectfully traverse these rejections for the reasons set forth below.

Contrary to the Examiner's assertion, there is no teaching or suggestion of using a "fluidized" flat bed oven in Gennaro. Gennaro teaches two distinct types of conventional drying techniques: "tray drying" and "fluidized bed" drying. Gennaro states that "[w]hile tray drying was the most widely used method of drying tablet granulations in the past, fluidized bed drying is now equally popular." (p. 1623). It is important to note that the reference to "fluidized bed

drying" in Gennaro in no way discloses or suggests "*horizontal* fluidized bed drying" as required by independent claim 23, which now incorporates the limitations of original claim 25. Rather, Gennaro is using the term "fluidized bed" synonymously with the conventional technique of *vertical* fluidized bed drying.

The enclosed Declaration of Dr. Gregory Urbanski explains that one skilled in the art would recognize that the disclosure of "fluidized bed" granulation and drying in Gennaro refers to "vertical fluidized bed" techniques and not "horizontal fluidized bed" drying as recited in claim 23. This is clear from Figure 12 of Gennaro which illustrates three common vertical "fluidized-bed granulation and drying" systems, labeled A, B and C. (p. 1624). Each apparatus in Figure 12 comprises a vertical chamber of cylindrical design in which the material to be granulated or dried is suspended "in a vertical column with a rising air stream" (p. 1625).

As explained in Gennaro, the use of such a fluidized-bed granulation and drying system "yields a less dense particle than conventional methods, and this can affect subsequent compression behavior." (emphasis added) (p. 1625). Thus, the particle density which would be achieved by high shear mixing is sacrificed upon drying.

In stark contrast to the conventional (i.e., vertical) fluidized-bed techniques described in Gennaro, the inventors of the present application unexpectedly discovered that drying granulation in a "horizontal fluidized bed oven" provides high density, highly compressible granulations. For instance, Examples I-VI of the application describe drying calcium carbonate granulation in a horizontal fluidized bed oven to yield particles having a tap density ranging from about 1.0 to about 1.31 g/cm^3. The Carrier model QAD/C 1260 S horizontal fluidized bed used in the examples is illustrated in Appendix A of the Declaration of Dr. Urbanski. As Explained in the Declaration, the illustration is reproduced from the operating

manual prepared by Carrier Corporation for Delavau, LLC, the assignee of the present application. As can be seen from the illustration, the horizontal fluidized bed oven is substantially different from the vertical fluidized bed ovens of Gennaro in both design and operation. The Carrier model QAD/C 1260 S horizontal fluidized bed oven comprises a perforated deck along which the granulation is fluidized transversely with respect to the direction of flow primarily by vibration. The granulation is only minimally displaced from the deck by the fluidizing action of the vibrating deck. The product is dried by primarily by convection of warm air.

The unexpected benefits of the method embodied in independent claim 23 are believed to arise because the dense particles formed by mixing under high shear in step (1) are permitted to dry essentially under their own weight, i.e., without substantial forced air flow, and without agglomeration during the horizontal fluidized bed drying of step (2).

Dr. Urbanski explains that, in view of the fact that vertical fluidized bed drying and granulation is known in the art to produce low density granulation, as recognized by Gennaro, one skilled in the art would not have been motivated to employ any fluidized bed drying in efforts to provide high density granulation.

Applicants respectfully submit that Gennaro does not teach or suggest a process for preparing high density granulation comprising the steps of (1) mixing a composition in a high shear mixer; and (2) drying the composition in a horizontal fluidized bed oven, as recited in claim 23 of the present application.

Neither U.S. Patent No. 5,637,313 to Chau et al. nor U.S. Patent No. 4,812,303 to Iorio rectify the deficiencies of Gennaro as these patents also do not teach or suggest granulating

under high shear mixing followed by horizontal fluidized bed drying. Chau et al. is directed to a "soft, chewable dosage form." The ingredients are said to be mixed in a high shear mixer, however there is no disclosure of a drying step. Rather, the examples teach that the mixture is "allowed to cool to room temperature" and then "rolled to desired thickness and cut into tablets of desired size." [col. 6, lines 32-35]. Not only does Chau et al. not disclose a drying step, one skilled in the art would appreciate that Chau et al. does not disclose any granulation technique whatsoever. Similarly, Iorio does not disclose a granulation process but rather appears to employ direct compression techniques for formation of tablets having a density "as low as possible." [col. 4, lines 46-47]. Further, the compositions of Iorio comprise only solid, dry ingredients, *viz.*, calcium carbonate, fumaric acid, and calcium lactate ("dried form"), obviating the need for any drying step. See [col. 6, lines 9-16]. In sum, because Chau et al. and Iorio do not disclose a drying step, teach away from highly compacted tablets, and do not relate to granulation processes, one skilled in the art, seeking to provide high density granulations, would not be motivated to look to these patents for any teaching whatsoever.

CONCLUSION

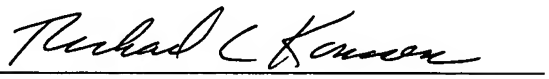
Applicants respectfully submit that this application is in condition for allowance. If a telephone conference would facilitate prosecution of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 13-4500, Order No. 4517-4002. Furthermore, in the event that an extension of time is required, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-noted Deposit Account and Order No. 4517-4002. A DUPLICATE OF THIS DOCUMENT IS ATTACHED.

Respectfully submitted,
MORGAN & FINNEGAN, L.L.P.

Dated: May 18, 2006

By: 

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